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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,022	01/29/2002	Frank Runge	52141	2669

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EXAMINER
SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	10/058,022	RUNGE ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communicati n appears n the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Application

Receipt of the Preliminary Amendment filed 01/29/02, the Change of Address filed 04/23/02 and the Information Disclosure Statement (IDS) filed 05/24/02 is acknowledged.

Claims 1-15 are pending. Claims 5, 6, 10, 12 and 15 have been amended. Claims 1-15 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.

Claim 15 provides for the *use of the carotenoid-containing dry powders*, but the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153

USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 15 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because step (a) does not recite any solvent in the step, whereas step (b) recites removing any additionally used solvents. Clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6, 7 and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen *et al.* (WO 91/06292) alone or in view of Horn *et al.* (US Pat. No. 4,522,743).

Jensen teaches a process for preparing powders comprising water dispersible hydrophobic or aerophilic powdered colorants – carotenoids, wherein the solids (carotenoids) are milled in an aqueous medium in the presence of a hydrocolloid to obtain a suspension containing suspended particles, finely dividing and drying the suspension to obtain a powder, whereby soybean protein is used as a suitable protective hydrocolloid and sucrose is contained in the aqueous medium (see reference pages 1, 4, 5, examples on pgs. 8-14 and abstract).

Solid hydrophobic/aerophilic materials that can be milled and encapsulated in the process are carotenoids, such as Beta-carotene, lutein, beta-apo-8'-carotenal,

canthaxanthin, astaxanthin, citranaxanthin, derivatives thereof and the like (page 4, lines 25-33).

Hydrocolloids that can also be used include exudates, extracts from seaweed, extracts from plants, extracts from marine and terrestrial animals, such as gelatins and other proteinaceous hydrocolloids, flours from seeds, such as soya bean and proteins from seeds, such as soya bean protein, etc. (pg. 4, line 35 thru pg. 5, line 9).

The aqueous medium can further contain excipients in an amount of up to 70 percent by weight of the suspension, such as a dissolved carbohydrate, such as sorbitol and sucrose, and/or an antioxidant or oil containing an antioxidant. The resulting suspension is finely divided and dried using any combination of conventional methods, such as spray cooling, spray drying, modified spray drying or sheet drying, crushing, etc. (page 5, lines 19-26).

In the spray cooling, spray drying and modified spray drying processes, excipients that may be used are, for example, starches, modified starches, *lactose*, mannitol, ethyl cellulose, etc. (pg. 6, line 39 thru pg. 7, line 5).

Jensen states that the amounts of the hydrophobic/aerophilic solids (carotenoids) are used in an amount of up to 71% (pg. 3, lines 5-13). This amount meets the applicant's claimed range of from 0.1 to 30% by weight.

The carotenoid preparation may be used in pharmaceutical compositions, foods and feedstuffs (pg. 8, lines 1-7).

Example 1 demonstrates the teaching of a milled suspension using a carotenoid - Beta-carotene in a solution mixture with sucrose, ascorbyl palmitate and tocopherol

(page 8). Example 6 provides canthaxanthin in a solution with sucrose having a temperature of 65°C.

Jensen's patent is lacking in the sense that he teaches sucrose, rather than lactose in a mixture with a hydrocolloid. However, lactose is a well-known protein stabilizer conventionally used by one skilled in the art. Such skill is also evident from the reference of Horn et al. (see below).

Horn *et al.* ('743) teach a process for preparing a finely divided pulverulent carotenoid composition wherein sugar or sugar alcohols, such as sucrose and lactose are advantageously added to the colloid in order to increase the mechanical stability of the end product (see reference col. 3, lines 27-39).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Horn within Jensen, because Horn explicitly teaches that it is advantageous to add lactose or sucrose to a colloid, which functions to increase the mechanical stability of the end product and similarly Jensen teaches a process utilizing carotenoids in a mixture with sugars or sugar alcohols, such as sucrose. One skilled in the art would be further motivated to use either lactose or sucrose in admixture with a carotenoid, since they are functionally equivalent as taught by Horn. The expected result would be a mechanically stabilized carotenoid composition.

Claims 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen *et al.* (WO 91/06292) in view of Dobler *et al.* (WO 96/01570).

The teachings of Jensen have been discussed above.

Jensen does not teach a partially degraded soybean protein having a degree of hydrolysis of from 0.1 to 20%

Dobbler teaches protective colloids for fat-soluble active substances (carotenoids), wherein the protective colloids are partially degraded soybean proteins having a degree of hydrolysis (degradation) of 0.1 to 5% (pg. 3, lines 4-8).

Therefore it would have been obvious to one of ordinary skill in the art to use the combined teachings of Dobler within Jensen because Dobler explicitly teaches a carotenoid composition containing partially degraded soybean proteins with a degree of hydrolysis of 0.1 to 5% (instant range recites 0.1 to 20%) and similarly Jensen teaches a cartenoid/hydrocolloid preparation and process for preparing whereby soybean protein is used as the suitable protective hydrocolloid. The expected result would be an effective carotenoid formulation having improved stability.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobler *et al.* (WO 96/01570) alone or in view of Horn *et al.* (US Pat. No. 4,522,743).

Dobler teaches partially degraded soybean proteins as protective colloids for carotenoids wherein water-dispersible compositions are produced with soybean

proteins and protective colloids in an aqueous medium and whereby glucose is contained in the aqueous medium to obtain a resulting dry powder (see reference pages 1-4 and examples).

According to Dobler, an objective of the invention is to find suitable protective colloids for fat-soluble active substances that do not involve technical disadvantages for processing and make it possible to produce in a simple way, stable, coldwater-dispersible compositions of fat-soluble active substances (carotenoids) (pg. 2, line 45 thru pg. 3, line 2).

Dobler teaches that the protective colloids for fat-soluble active substances (carotenoids) are partially degraded soybean proteins, which have a degree of hydrolysis (degradation) of 0.1 to 5% (pg. 3, lines 4-8).

The soybean proteins usually employed are commercial soybean protein isolates and concentrates with protein contents of from 70 to 90% by weight, where the remaining 10 to 30% by weight represent other undefined plant constituents. The soybean protein isolates are incubated with the enzyme in aqueous medium, preferably at from 50 to 70°C and at a pH of from 7 to 9. The suitable protein to enzyme ratio for the desired degree of degradation (hydrolysis) can be determined by laboratory tests which are simple for the skilled worker (pg. 3, lines 24-32).

Suitable fat-soluble active substances are carotenoids, for example, Beta-carotene, apocarotenal, ethyl apocarotenoate, canthaxanthin, zeaxanthin, astaxanthin, lycopene, citranaxanthin or mixtures of said substances (pg. 3, lines 38-43).

The fat-soluble active substances can be added to the compositions either in pure form or as a mixture with physiologically tolerated oils (i.e., sesame oil, soybean oil, corn oil, etc.). In addition to the fat-soluble active substances and the partially degraded soybean proteins, the compositions may also contain conventional auxiliaries, for example, sugars and sugar alcohols, starch and derivatives, stabilizers and emulsifiers (pg. 4, lines 1-11).

The compositions can be either in liquid or solid form, however solid compositions are preferred. Spray drying or spray fluidized bed drying can be used to produce the solid compositions. The fat-soluble active substances are contained in amounts from 2 to 40% of the total weight of active substance and protective colloid (pg. 4, lines 21-29). This range meets the applicant's claimed amounts of 0.1 to 30% carotenoid content.

According to Dobler, the compositions are outstandingly suitable for use in livestock nutrition, as an additive to foodstuffs or as an addition to drinking water. Carotenoid-containing compositions are also suitable as foodstuff colorants, especially for soft drinks (pg. 4, lines 34-40).

The examples on pages 5-7 demonstrate a process for preparing dry powders comprising protective colloids - soybean proteins in a mixture solution with various carotenoids and glucose. For instance, example 4 provides a dispersion of citranaxanthin with soybean protein isolate and glucose to obtain a dry powder containing 3.0% citranaxanthin content.

Although Dobler is lacking in the sense that he teaches glucose, rather than lactose in combination with soybean protein and carotenoids, one of ordinary skill in the art would be able to substitute glucose for lactose to obtain similar results. Such skill is also evident from the reference of Horn et al. (see below).

Horn *et al.* ('743) teach a process for preparing a finely divided pulverulent carotenoid composition wherein sugar or sugar alcohols, such as glucose and lactose are advantageously added to the colloid in order to increase the mechanical stability of the end product (see reference col. 3, lines 27-39).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Horn within Dobler, because Horn explicitly teaches that it is advantageous to add either lactose or glucose to a colloid, which functions to increase the mechanical stability of the end product and similarly Dobler teaches a process utilizing carotenoids in a mixture with sugars or sugar alcohols, such as glucose. One skilled in the art would be further motivated to use either lactose or glucose in admixture with carotenoids, since they would be functionally equivalent and provide a similar outcome, as taught by Horn. The expected result would be a mechanically stabilized carotenoid composition.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703)

308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
August 8, 2003

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